

3 tenth computer readable program code means for causing the computer to generate an  
4 initial shift schedule for each of said plurality of preparation vessels; and  
5 a2 eleventh computer readable program code means for causing the computer to generate  
6 a final shift schedule for each of said plurality of preparation vessels by back scheduling at  
7 least one solution associated with said initial shift schedule in order to resolve conflicts  
8 between solution preparation cycles for each of said plurality of preparation vessels and shifts  
of the biopharmaceutical production process.--

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**Remarks**

Reconsideration of this Application is respectfully requested.

Claims 1-2 and 4-17 are pending in the application, with claims 1, 4, 10 and 12 being the independent claims. Claims 1 and 2 have been amended, and claim 3 has been canceled without prejudice or disclaimer. New claims 4-17 have been added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

**I. New Claims**

New claims 4-17 have been added. Claims 4-9 are new method claims and claims 12-17 are the corresponding computer program product claims (see new title). New claims 10-11 are computer program product claims and corresponding to claims 1 and 2, respectively. The support for these claims can be found, for example, in the Specification at pages 32-54 and figures 13-32. Thus, these changes are believed to introduce no new matter.

**II. Rejections Under 35 U.S.C. § 112**

In paragraph 2 of the Office Action, the Examiner rejected claims 1-3 under 35 U.S.C. § 112, ¶ 2 as being indefinite. Thus, claims 1 and 2 have been amended in order to more particularly point out and distinctly claim the subject matter which the Applicant regards as his invention, and claim 3 has been canceled without prejudice or disclaimer.

### **III. Rejections Under 35 U.S.C. § 103**

The Examiner rejected claims 1-3 under 35 U.S.C. § 103(a) as being unpatentable over Skeirik, Athernon, Iwasaki *et al.*, Litt *et al.*, Furukawa *et al.*, or Carrette *et al.*, in view of taking official notice. See Office Action at ¶ 4.

More specifically, the Examiner contends that “hundreds of patents regarding the modeling of process control and scheduling” exist. Office Action at ¶ 5. The Examiner further stated that:

[Skeirik, Athernon, Iwasaki *et al.*, Litt *et al.*, Furukawa *et al.*, or Carrette *et al.*] disclose all the limitations of the claims *except that they do not disclose details concerning identifying, assigning, and calculating the volume of a solution which is to be processed.* However, official notice is taken that it would have been obvious to one of ordinary skill in the art at the time of the invention that such details would be included when scheduling control of chemical or biopharmaceutical processing.

Office Action at ¶ 12 (emphasis added). This rejection is traversed below.

First, the Applicant would like to point out that the present invention, in the preferred embodiment, is directed to a computer based system and method for the simulation, modeling and scheduling of batch process solution preparation. The preferred embodiment is based on a method for generating scheduling information which accurately defines the complex manufacturing operations of solution preparation in batch manufacturing processes. This allows the definition of manufacturing costs and systems in a more detailed and accurate manner than previously possible. As a result, this invention allows the rapid and accurate evaluation of numerous batch manufacturing alternatives in order to arrive at an optimal process design early in a facility development project. In so doing the invention minimizes project cost over runs which result from inaccuracies that can carry forward from the early stages of design into construction of a manufacturing facility.

As the Examiner correctly pointed out, each of the six above-mentioned references were cited by the Applicant in an Information Disclosure Form. The references all deal with real-time process control for manufacturing facilities. In contrast, the present invention is directed to simulating the scheduling of solution preparation in a biopharmaceutical production process in order to arrive at an optimal facility design. The Examiner will now find that the present

invention, as summarized above and now more particularly claimed in amended claims 1-2 (and new claims 4-17), is not obvious in light of these references either taken alone or in combination.

### *Conclusion*

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all currently outstanding rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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